

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Shirley Xiaoli Guo
Robert W. Harriman
Lisa Lee
Eric K. Nelson

Serial No. 10/537,393

Filed: July 27, 2005

Confirmation No. 2098

For: **BENTGRASS EVENT ASR-368 AND**
COMPOSITIONS AND METHODS FOR
DETECTION THEREOF

§
§ Group Art Unit: 1638
§
§ Examiner: David H. Kruse
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§ Attorney Docket Number 11899.0236.PCUS00
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DECLARATION RE REQUEST FOR INFORMATION UNDER 37 C.F.R. § 1.105

Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, Virginia 22313-1450, on the date below:	
<u>April 17, 2008</u> Date	<u>Claudia A. Standiford</u> Claudia A. Standiford

Sir:

In response to the Request for Information under 37 CFR §1.105 attached to the Office Action dated July 5, 2006, Applicants submit the following information as requested in the form of a declaration under 37 CFR §1.132.

Serial No. 10/537,393

Declaration of M. Todd Rands Under 37 CFR §1.132

I, M. Todd Rands, declare the following:

1. I have been employed by Monsanto Technology LLC (hereinafter "Monsanto" or "MONSANTO") since September 2004. My position carries with it the responsibility of providing legal advice in the fields of commercial and intellectual property law to various business enterprises within Monsanto. A principle role in this position includes drafting and managing various licenses and other agreements between Monsanto and third parties relating to herbicide-tolerant and other transgenic crops.

2. I have read, I understand, and I am familiar with the issues with respect to the Request for Information under 37 CFR §1.105 attached to the Office Action dated October 18, 2007 in the above captioned application. I also understand that the request is being made because the Federal Register Vol. 69, No. 2, pp 315-317, Monday, January 5, 2004 discloses that ASR368 bentgrass has been field tested since 2000 in the United States under APHIS notifications. I also understand that the effective filing date for the above captioned application corresponds to the date the provisional application, to which the above captioned application claims priority, was filed, and that the provisional application was filed on December 5, 2002.

3. As a result of my employment with Monsanto Company and the nexus that my employment positions have had with respect to the development and commercialization of the referenced transgenic event ASR-368, it is my belief that there was no sale or other public use or distribution by Monsanto of the claimed plant anywhere in the United States more than one year prior to the effective filing date of the above captioned application. That is, there was no sale or

other public use prior to the filing date of the provisional application SN 60/431153, filed on December 5, 2002.

4. In connection with developing plans related to the development and commercialization of the transgenic bentgrass event ASR-368, Monsanto Company entered into development agreements (hereafter "Agreements") with The Scotts Company (hereafter "Scotts" or "SCOTTS") and Sanford Scientific, Inc. (hereafter "Sanford"). As a result of my employment with Monsanto and the nexus which my employment positions have, I have reviewed and am familiar with the terms and conditions of the agreements titled:

- a. "Transgenic Plants Commercial Agreement", effective December 9, 1998;
- b. "Restated Transgenic Plants Commercial Agreement", last executed January 11, 2001; and
- c. "Restated Collaboration Agreement", last executed January 17, 2001

Under the provisions of the aforementioned Agreements, Scotts' and Sanford's shall not commercialize transgenic plants including, turfgrass "unless and until it has first obtained the written approval of Monsanto".

To my knowledge and belief, so far as Monsanto is aware, there was no sale or public use or public distribution by Scotts, or Sanford of the claimed plant anywhere in the United States prior to the December 5, 2002, effective filing date of the above captioned application.

6. The APHIS Petition that the Examiner refers to in the attachment to the above mentioned Office Action states that the event ASR-368 was released for field trials in the United States since 2000. It should be understood that this and all subsequent releases of regulated seed were made *only* under the provisions set forth in the Regulatory Compliance Packages provided with each release to recipient. These field trial releases were all federally regulated and subjected to strict compliance requirements. To my knowledge, regulated seed corresponding to

the event ASR-368 were only provided to recipient by Monsanto Company/Scotts or by companies under contract with Monsanto Company and at Monsanto Company's instructions. Prior to or contemporaneous with the receipt of any regulated seed, each recipient was provided with a Regulatory Compliance Package and a Study Protocol containing instructions for conducting studies using the regulated transgenic seed. Because the regulated transgenic seed were restricted articles under USDA and EPA regulations, strict compliance with regulatory procedures set forth in the Compliance Packages was required of all recipients. Regulated transgenic seed were only shipped to a recipient upon receipt by Monsanto of a USDA Interstate Movement and Release Permit. Each Study Protocol provided the following notice to the recipient of the regulated seeds:

All information regarding the identity of the test substance(s), associated samples, and data must be kept strictly confidential. No raw data, worksheets, observations, data or information summaries, reports, or other information related to this study may be revealed or released to any third party without prior notification and authorization of Monsanto Company.

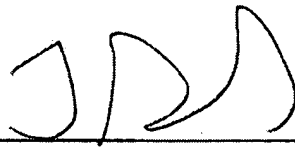
Regulatory Compliance Packages provided to recipients of the regulated transgenic seed notified each recipient of his or her obligations under federal regulations for such regulated articles, requiring that the recipients restrict access to the seed and materials generated from the seed, restrict movement of the seed or plant materials grown from the seed, maintain the seed and the plots where the seed were sown under secure conditions, insure that the seed and any plants or produce from the plants be kept from entering into any stream of commerce, isolate fields where the seed are planted to restrict the movement of pollen to related species, destroy remaining plant material in fields where the seed were planted, limit replanting in consecutive seasons in the same field and monitor for and destroy volunteer plants that grow in subsequent seasons, and report to Monsanto Company any alterations or deviations from these requirements

so that such information reported by a recipient could also be reported to the appropriate federal regulatory authorities requiring such compliance standards. Upon the conclusion of any such regulated field trials, the recipients of such regulated seed were required to execute a statement acknowledging that he/she had received, read, and understood the Monsanto company and USDA Compliance Package for each regulated trial being conducted for Monsanto Company and complied with the principles and policies set forth in the USDA Compliance Package.

7. The Examiner has also requested information about distributions outside the United States. To my knowledge, no distribution by Monsanto was made prior to one year before the filing of the instant application.

8. Therefore, based on my knowledge regarding this transgenic event and its development, the regulatory approval process through which the event traversed, its commercialization history, and the facts that I declare herein above, it is my opinion that no sale or offer for sale for the ASR-368 transgenic bentgrass event was made more than one year prior to the effective date of the instant application, and that there was no public use of this material more than one year prior to the effective date of the instant application.

9. I hereby declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



M. Todd Rands

Date: 17 April 2008

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Monsanto Company BBIL
Attn: E. Clifford Lawson
700 Chesterfield Pkwy
Chesterfield, MO 63198

Deposited on Behalf of: Monsanto Technology LLC

Identification Reference by Depositor:

Patent Deposit Designation

Medicago sativa, Alfalfa: J101
(Ref: Case No.: 38-21(53220))
Medicago sativa, Alfalfa: J-163
(Ref: Case No.: 38-21(53220))
Bentgrass (Agrostis stolonifera): ASR368
(Ref: Case No.: 38-21(53216))

PTA-4814

PTA-4815

PTA-4816

The seeds were accompanied by: a scientific description a proposed taxonomic description indicated above. The seeds were received November 22, 2002 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the seeds for 30 years.

The seeds will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the seeds and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said seeds.

If the seeds should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with viable seeds of the same.

The seeds will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the seeds cited above was tested December 2, 2002. On that date, the seeds were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: January 6, 2003

cc: Grace Bonner
(Ref: Docket or Case No.: 38-21(53220))



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Shirley Xiaoli Guo
Robert W. Harriman
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Eric K. Nelson

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§ Attorney Docket Number 11899.0236.PCUS00
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DECLARATION OF BIOLOGICAL CULTURE DEPOSIT

Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

CERTIFICATE OF MAILING	
37 C.F.R. 1.8	
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<i>April 17, 2008</i> Date	<i>Claudia A. Standiford</i> Claudia A. Standiford

Sir:

I, M. Todd Rands, hereby declare that I am an attorney of record in the United States Patent and Trademark Office for the above-referenced application, and am authorized to sign for the Assignee of Interest, Monsanto Technology LLC, in this matter. I have reviewed the Biological Culture Deposit Receipts on which I have based the following statements.

1. The following material referred to in the specification of the above-referenced application has been deposited with the American Type Culture Collection (ATCC):

<u>TAXONOMIC DESCRIPTION</u>	<u>IDENTIFICATION REFERENCE</u>	<u>DEPOSIT NUMBER</u>
bentgrass event ASR-368	bentgrass plant ASR-368	PTA-4816

2. The date of the above deposit is on or before the U.S. filing date of this application.

3. The name and address of the depository is:

American Type Culture Collection (ATCC)
10801 University Boulevard
Manassas, Virginia 20110-2209

4. With respect to the permanence of the culture deposit:

a. the depository is an official depository in accordance with the Budapest Treaty for the above-deposited culture;

b. the depository affords permanence of the deposit for at least thirty (30) years or at least five (5) years after the most recent storage request, whichever is longest; and

c. evidence that permanent availability of the microorganism is assured as provided in the form of the attached copy of the contract with the above-mentioned depository with respect to the deposited culture.


In the event that the microorganisms mutate, become nonviable, or are inadvertently destroyed, the Assignee of Interest will replace such microorganisms for at least thirty (30) years from the date of the original deposit, or at least five (5) years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, plus six (6) years to cover the statute of limitations, whichever period is longer.

Serial No. 10/537,393
Declaration of Biological Culture Deposit

5. With respect to availability of the cultures, the deposit has been made under conditions of assurance that, during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request, and all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed from the granting of a patent on this application.

6. All statements made herein are believed to be true and correct; and these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

MONSANTO TECHNOLOGY LLC

By 
M. Todd Rands, Esq.
Intellectual Property Counsel

Date 17 April 2008

Monsanto Company
800 North Lindbergh Boulevard
St. Louis, Missouri 63167